



PATENT

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Placke, Michael E., <i>et al.</i>	Group No: 1618
Serial No: 10/066,831	Examiner: Pryor, Alton N.
Filed: 02/04/2002	
For: Formulations and Methods for Treating Neoplasms By Inhalation	

Commissioner for Patents
P.O. Box 1450
Alexandria VA 22313-1450

Dear Sir:

DECLARATION OF JAMES N. ALLEN, Jr., M.D.

I, James N. Allen, Jr., M.D., 4215 Mumford Ct., Columbus, OH 43220, United States of America, hereby declare the following:

- I am Professor of Internal Medicine in the Division of Pulmonary and Critical Care Medicine at The Ohio State University Medical Center, Columbus, Ohio.
- I received a B.A. Degree *magna cum laude* from Miami University, Oxford, Ohio in 1980; I received a M.D. Degree from The Ohio State University in 1984; I was Chief Residency in Internal Medicine, Ohio State University Hospitals from 1988-1989 and held a Fellowship in Pulmonary and Critical Care Medicine, Ohio State University Hospitals from 1987-1991.
- I am a Diplomate of the American Board of Medical Examiners, a Diplomate of the American Board of Internal Medicine, a Diplomate of the American Board of Internal medicine, Pulmonary Disease, and a Diplomate of the American Board of Internal Medicine, Critical Care Medicine.
- I am a member of the American College of Chest Physicians, American Thoracic Society, Ohio Thoracic Society, American College of Physicians, National Association for the Medical Direction of Respiratory Care, International Society of Cryosurgery, American College of Physician

Executives, Society for Critical Care medicine, and the Association of Professors of Medicine.

- I have authored or co-authored 3 book chapters, over 80 papers and abstracts, and have made presentations at 18 national meetings, e.g., American Academy of Asthma, Allergy, and Immunology Annual Meeting 2005.
- A comprehensive listing of my education, training, and accomplishments is set forth in my *Curriculum Vitae* attached to this Declaration.
- I have read and understand the claims of the Placke, *et al* application ("Invention Claims") which are presently before the United States Patent Office (USPTO).
- I have read and understand that portion of Examiner's Final Office Action, Paper #7, dated 09/22/2003 and the Office Action dated 04/22/2005 (the "Actions") where the Examiner rejects the Invention Claims as obvious to one skilled in the art because US 5,770,585 (Kaufman *et al*) teaches:
 "a method of treating lung cancer (respiratory cancer) comprising delivering a liquid dispersion (aerosol liquid) or breathable gas (inhalation) containing an anthracycline such as doxorubicin to the lungs".
- I have read and understand the text and claims of US 5,770,585 (Kaufman *et al*) and specifically Claims 11 and 12. As I understand Claim 11 of Kaufman, no specific method of administration of the water-in-oil ("w/o") perfluorocarbon emulsion is stated. However, based on the text of Kaufman, it is clear to me that Kaufman intends the liquid perfluorocarbon emulsion to be administered to the lungs of an animal by instillation of the liquid intratracheally. I base this belief on the disclosure at Col's 4-6 and especially at Col. 6, lines 53- 61 of the Kaufman patent which describes the intratracheal administration of an anti-cancer agent such as doxorubicin
- I read Claim 12 of the Kaufman patent to mean an animal being treated as described in Claim 11 may be on a mechanical ventilator during the administration of the liquid perfluorocarbon emulsion to the lungs of the animal. In my opinion, the combined method of Claim 11 and Claim 12 of Kaufman is described by the protocol set forth at Col 8 of Kaufman.
- Briefly, the protocol set forth in the Kaufman patent describes the following procedure. The test animal (rat) was first catheterized to allow for withdrawal of blood from the right carotid artery for the purpose of taking blood for determination of blood gases. Next, an endotracheal tube ("ET") was placed in the trachea of the animal and the hub of the ET was connected to a rodent ventilator with the respiration rate set at a predetermined rate. Blood gases were taken and the animal was disconnected from the rodent ventilator. The w/o liquid perfluorocarbon emulsion saturated with 100% oxygen was instilled into the lungs of the rat in an amount equal to 30 ml/kg of body weight. The

animal was reconnected to the ventilator and arterial blood gas samples were collected at time intervals. After about 30 minutes, the rat was disconnected from the ventilator and the liquid perfluorocarbon emulsion was drained from the lungs of the rat by gravity and the liquid was collected. The animal was reconnected to the ventilator and blood was drawn for blood gas determination 5 minutes later; thereafter, once the animal showed signs of spontaneous respiration it was taken off the ventilator and the ET was removed from the trachea.

- Based on my training and experience, the method detailed by the protocol of Kaufman is commonly referred to as partial liquid ventilation (PLV). Partial liquid ventilation involves filling the lungs of a patient with a liquid perfluorocarbon usually, perflubron. The liquid may be placed in the lungs via an endotracheal tube and thereafter the patient is connected to a conventional gas ventilator or the perfluorocarbon liquid is trickled into the lungs of a patient connected to a ventilator through a side-port on the endotracheal tube connecting the patient to the ventilator. To my knowledge, PLV is currently being studied for a variety of acute lung injuries.
- In my opinion, the Kaufman patent does not describe a method of administering the liquid perfluorocarbon emulsion of the Kaufman invention to the lungs of an animal in the form of an aerosol. In medicine, an aerosol is a fine mist or cloud which contains minute particles of the active drug substance; the mist is inhaled into the respiratory tract of the patient for treatment of a disease or condition. Kaufman administers the active drug substance as part of a liquid perfluorocarbon emulsion. This liquid emulsion is not the same as a medicinal aerosol.

I further declare that all statement made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the above-identified application or any patent issuing thereon.

Date: September 23, 2005

By: James N. Allen, Jr., M.D.





Curriculum Vitae

JAMES N. ALLEN, Jr., M.D.

ADDRESS:

Division of Pulmonary and Critical Care Medicine
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201 Heart Lung Institute
473 West 12th Ave.
Columbus, Ohio 43210
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EDUCATION:

B.A., *magna cum laude*; Miami University; Oxford, Ohio; 1980.

M.D., Ohio State University; Columbus, Ohio; 1984.

Internship and Residency in Internal Medicine, Ohio State University Hospitals:
1984-1987.

Chief Residency in Internal Medicine, Ohio State University Hospitals:
1988-1989.

Fellowship in Pulmonary and Critical Care Medicine, Ohio State University
Hospitals: 1987-1991.

ACADEMIC & ADMINISTRATIVE POSITIONS:

Professor of Clinical Medicine, Division of Pulmonary and Critical Care
Medicine, 2003 - present

Associate Professor of Medicine, Division of Pulmonary and Critical Care
Medicine, The Ohio State University, 1997 - 2003.

Assistant Professor of Medicine, Division of Pulmonary and Critical Care
Medicine, The Ohio State University, 1991 - 1997.

Medical Director, Pulmonary Diagnostics Laboratory, Ohio State University
Hospitals, 1995 - present

Medical Director, Medical Intensive Care Unit, Ohio State University Hospitals,
1997 - 2001

Co-Director, Medical Intensive Care Unit, Ohio State University Hospitals,
2001-2004

Associate Clinical Director, Division of Pulmonary and Critical Care Medicine,
1996 - 2002

Associate Medical Director, Select Specialty Hospital of Columbus, 1996 - present

Editor and Moderator, Ohio Medical Education Network (OMEN-TV), 1998 - 2002

Editor and Moderator, Ohio State University MedNet, 2002 - present

Treasurer, Department of Medicine Foundation of Ohio, 2001 - present

Chief of Internal Medicine at Ohio State University East Hospital, 2003 - present

Vice Chairman for Clinical Program Development, Ohio State University Department of Internal Medicine, 2003 - present

BOARD CERTIFICATION:

Diplomate of the American Board of Medical Examiners, 1985.

Diplomate of the American Board of Internal Medicine, 1987 (lifetime certificate).

Diplomate of the American Board of Internal Medicine, Pulmonary Disease, 1990 (certificate valid through 2000). Recertification, 2000 (certificate valid through 2010).

Diplomate of the American Board of Internal Medicine, Critical Care Medicine, 1991 (certificate valid through 2001). Recertification, 2000 (certificate valid through 2010).

PROFESSIONAL SOCIETY MEMBERSHIPS:

American College of Chest Physicians, 1986-present (FCCP 1994).

American Thoracic Society, 1988-present.

Ohio Thoracic Society, 1988-present.

American Federation for Medical Research, 1991-2000

American College of Physicians, 1993-present.

National Association for the Medical Direction of Respiratory Care, 1997-present

International Society of Cryosurgery, 2000-present

American College of Physician Executives, 2001-present

Society for Critical Care Medicine, 2003 - present

Association of Professors of Medicine, 2003 - present

HONORS AND AWARDS:

Psi Chi, 1978.

Patton Prize, Miami University, 1980.

Phi Beta Kappa, 1980.

Alpha Omega Alpha, 1983.

Ohio State University College of Medicine Teaching Award, 1986.

Ohio State University College of Medicine Teaching Award, 1987.

Ohio State University Department of Internal Medicine Award of Merit, 1987.

James V. Warren Award for Fellowship Research, Ohio State University, 1991.

Ohio State University Department of Internal Medicine Teacher of The Year Award, 1994.

OMEN TV Best Team Clinical/Surgical Presentation of 1994-95.

Ohio State University CME Award of Excellence, 1994-95.

OMEN TV Best Clinical Presentation of 1995-96.

Professor of the Year, Ohio State University College of Medicine, 1996.

Crystal Cross Award, American Lung Association of Ohio, 1997

Named among "The Best Doctors in America", Woodward/White, Inc., 1998

Named among "The Top Doctors in Columbus", Columbus Monthly Magazine, 1998

Ohio State University College of Medicine Teaching Award, 2000

Battelle Professor of Inhalational Therapeutics, 2000

Ohio State University Department of Internal Medicine Teacher of The Year Award, 2001

Ohio State University Department of Internal Medicine Teacher of The Year Award, 2003

Named among "The Best Doctors in America", 2003

Named among "The Top Pulmonologists in Columbus", Columbus Dispatch Newspaper, 2004

Ohio State University Department of Internal Medicine Teacher of The Year Award, 2004

Ohio State University Department of Internal Medicine Critical Care Teaching Award, 2005

Named among "The Best Doctors in America", 2005

RESEARCH GRANTS:

American Lung Association Fellowship Award, \$19,000, 1989: Principal Investigator (awarded but declined due to simultaneous award of the Parker B. Francis Fellowship)

Parker B. Francis Fellowship in Pulmonary Research, \$96,000, 1989-1992: Principal Investigator.

NIH Clinical Investigator Award (K08 HL02688-01): "Macrophage Microtubules During Inflammation", \$379,000, 1992-1997: Principal Investigator.

Davis Scholarship: "Macrophage Microtubules During Inflammation", \$17,800, 1992: Principal Investigator.

Bremer Foundation: "Characterization of the Anti-Inflammatory Properties of Pulmonary Surfactant", \$3,000, 1993-1994: Principal Investigator.

American Lung Association Fellowship Award: "The Effect of Surfactant on Macrophage Cytokine Production", \$65,000, 1993-1995: Sponsor for Amy Pope-Harman, M.D.

American Heart Association, Ohio Affiliate, Inc, Fellowship Award: "The Effect of Surfactant on Production of Myocardial Depressant Factors", \$60,000, 1993-1995: Sponsor for Amy Pope-Harman, M.D. (awarded but declined due to simultaneous award of American Lung Association Fellowship).

American Lung Association: "The Role of Microtubules in Macrophage Cytokine Production", \$50,000, 1993-1995: Principal Investigator.

Amgen Corporation: "A Phase II Trial of Taxol in Squamous Cell Carcinoma of the Head and Neck with Correlative Laboratory Studies", \$85,000, 1993: Co-Investigator.

NIH (HL53229): "Lymphocytic Alveolitis, IL-1 β , And Lung Injury", \$1,278,177 (total costs); 1994-1999: Co-Investigator.

Sandoz Research Scholarship: "Mononuclear Phagocyte CD43 Receptor and Malignancy", \$85,650, 1995-1997: Sponsor for Randal Seigel, M.D.

Merck Pharmaceuticals: "The Effect of Imipenem on Human Pro-Inflammatory Cytokine Production", \$8,288, 1996: Principal Investigator.

Ohio State University Medical Center: "An Evaluation Of Two Modes Of Care On Asthma Patient Outcomes: Pulmonologists Treating Asthma Patients With Or Without Support From A Pharmacist Education Program", \$10,000; 1996-1997: Co-Investigator.

Lincare Corporation: "A Randomized Trial Of BiPAP In Pulmonary Rehabilitation", 1996-1997: Principal Investigator.

Astra-Merck: "Asthma Reflux Trial", \$74,000; 1997-1998: Principal Investigator for Ohio State University Site.

Battelle Memorial Institute: "Feasibility, Tolerability and Deposition Study of 20% Ethanol (Vehicle and Tc-99m) Administered by Inhalation in Healthy Volunteers and Patients with Mild to Moderately Severe Respiratory Impairment Using a New Inhalation Device (CDD-1)" \$149,000 1997-1998: Principle Investigator.

Alliance Pharmaceuticals: "Multicenter, Prospective, Randomized, Controlled Pivotal Trial for Efficacy of Partial Liquid Ventilation (PLV) with Low and High

Doses of Perflubron in Adult Patients with Acute Lung Injury" \$87,000; 1999-2000: Co-Investigator for Ohio State University site.

Pharmacia & Upjohn: "Linezolid (PNU-100766) in the treatment of patient with nosocomial pneumonia: A double-blind, randomized, comparator-controlled study" \$11,250; 1999-2000: Principle Investigator for Ohio State University site.

Battelle Memorial Institute: "Feasibility, Tolerability and Deposition Study of Polyethelene glycol/ethanol Administered by Inhalation in Healthy Volunteers and Patients with Mild to Moderately Severe Respiratory Impairment Using a New Inhalation Device (CDD-2)" \$120,663; 1999-2000: Principle Investigator.

Ortho Biotech: "The Anemia of Critical Illness and Transfusion in the Critically Ill Patient". \$26,000; 2000-2001: Principle Investigator.

Altana/Byk-Gulden Corp.: "Venticute (rSP-C Surfactant) for the Treatment of Acute Respiratory Distress Syndrome (ARDS): A randomized, multinational, multicenter, parallel group, double blind controlled study". \$36,480; 1999-2000: Principle Investigator for Ohio State University site.

Glaxo Wellcome, Inc.: Effects of a corticosteroid-sparing dose of salmeterol/fluticasone propionate combination product. 2000-2001 \$20,185 Principle Investigator for the Ohio State University site.

Suntory Pharmaceuticals: A phase II multicenter randomized double blind placebo controlled parallel group dose ranging evaluation of the safety and efficacy of a-hANP infusion (Carperitide for injection; SUN4936)". \$50,000 estimated. 2001-2002 Principal Investigator for the Ohio State University site.

ICOS Pharmaceuticals: "Phase III study to demonstrate the safety and efficacy of recombinant platelet activating factor acetylhydrolase (is rPAF-AH, PAFHFE for reducing 28 day all cause mortality in patients with severe sepsis)". \$50,000 estimated. 2001-2002 Principal Investigator for the Ohio State University site.

BattellePharma, Inc.: "Study of the tolerability of 100% ethanol of 20% PEG300/80% ethanol vehicle administrated to subjects with known asthma using a new inhalation device (CDD-2)". \$145,225. 2002-2003. Principal Investigator.

Intermune, Inc.: "Actimmune (R) safe and appropriate use program." \$5,000. 2001-2003. Principal Investigator.

Pharmacia, Inc.: "Linezolid versus vancomycin or oxacillin/dicloxacillin in the Treatment of Catheter-related Gram-Positive Bloodstream Infections". \$45,000. 2002-2004. Principal Investigator.

BattelleParma, Inc.: "Phase I and clinical pharmacologic study of inhaled doxyrubicin in adults with advanced stage solid tumors affecting the lung". \$20,260. 2000-2003. Co-Investigator.

Eisai Medical Research, Inc: "E5564 -A001-201 A Double Blind, Placebo-Controlled, Study of E5564, in a Lipid A Antagonist, Administered by Twice Daily Intravenous Infusions in Patients with Severe Sepsis". 2003-2004. \$67,055. Principal Investigator.

Astra-Zenica: "Symbicort in asthma". 2003-2004. Principal Investigator.

Ohio BRTT: "A Comprehensive Program for the Prevention, Detection, and Treatment of Lung Cancer". 2003. \$8,000,000. Co-Investigator.

Altana: "Venticute (rSP-C Surfactant) in Patients with Pneumonia or Aspiration of Gastric Contents Leading to Intubation, Mechanical Ventilation, and Severe Oxygenation Impairment". 2003-2005. Principal Investigator.

Nabi Pharmaceuticals: "Initial safety and pharmacokinetics trial of immune globulin Staphylococcus aureus capsule polysaccharide (Altastaph) in subjects with S. aureus bacteremia and persistent fever. 2004-2005. Principal Investigator.

GlaxoSmithKline: "LIPOS-Lipid Infusion and Patient Outcomes in Sepsis". 2004-2006. Principal Investigator.

Intermune Pharmaceuticals: "A randomized, double-blind, placebo-controlled, phase 3 study of the safety and efficacy of interferon gamma-1b in patients with idiopathic pulmonary fibrosis (INSPIRE Trial)". 2004-2008. Principal Investigator.

PUBLICATIONS:

1. Allen J, Beaver B, Das M, Satiani B. Ergot-induced arterial ischemia. *Contemporary Surgery*. 1985; 7:41-5.
2. Allen JN. Actinomyces meyerii breast abscess. *American Journal of Medicine*. 1987; 83:186-7.
3. Allen JN, Gadek JE. Concepts of the pathogenesis of idiopathic pulmonary fibrosis: conflict and consensus. *Pulmonary Perspectives*. 1988; 5:2-3.
4. Allen JN, Gadek JE. Update on the evaluation and treatment of idiopathic pulmonary fibrosis. *Pulmonary Perspectives*. 1988; 5:1-4.
5. Allen JN, Wewers MD. HIV-associated bronchiolitis obliterans. *Chest*. 1989; 96:197-8.
6. Allen JN, Pacht ER, Gadek JE, Davis WB. Acute eosinophilic pneumonia as a reversible cause of respiratory failure. *New England Journal of Medicine*. 1989; 321:569-74.
7. Allen JN, Pacht ER, Gadek JE, Davis WB. Acute eosinophilic pneumonia. (letter) *New England Journal of Medicine*. 1990; 322: 636.
8. Allen JN, Wewers MD. Acute myocardial infarction with cardiogenic shock during pregnancy: treatment with intra-aortic balloon counterpulsation. *Critical Care Medicine*. 1990; 18:888-889.
9. Allen JN, Davis WB, Pacht ER. The diagnostic significance of bronchoalveolar lavage fluid eosinophilia. *American Review of Respiratory Disease*. 1990; 142:642-647.
10. St. John R, Allen JN, Pacht ER. Postoperative respiratory failure due to acute eosinophilic pneumonia. *Intensive Care Medicine*. 1990; 16:408-410.
11. Allen JN, Pacht ER. When to consider acute eosinophilic pneumonia. *Journal of Respiratory Disease*. 1991; 12: 11-16.
12. Allen JN, Herzyk DJ, Wewers MD. Colchicine has opposite effects on interleukin-1 beta and tumor necrosis factor-alpha production. *American Journal of Physiology: Lung Cellular and Molecular Physiology*. 1991; 5:L315-21.
13. Allen JN, Herzyk DJ, Allen ED, Wewers MD. Human whole blood interleukin-1

beta production: kinetics, cell source, and comparison with TNF-alpha. *Journal of Laboratory and Clinical Medicine*. 1992; 119:538-546.

14. Herzyk DJ, Berger AE, Allen JN, Wewers MD. Sandwich ELISA formats designed to detect 17 kDa IL-1 beta significantly underestimate 35 kDa IL-1 beta. *Journal of Immunological Methods*. 1992; 148:243-54.

15. Allen JN, Davis WB. What is eosinophilic pneumonia? *Archives of Internal Medicine*. 1992; 152:1765-6.

16. Herzyk DJ, Allen JN, Marsh CB, Wewers MD. Macrophage and monocyte IL-1 beta regulation differs at multiple sites: mRNA expression, translation, and posttranslational processing. *Journal of Immunology*. 1992, 149:3052-9.

17. Allen JN, Pacht ER. Defining the treatment options for chronic eosinophilic pneumonia. *Journal of Respiratory Disease*. 1993; 14: 816-7.

18. Allen JN, Moore SA, Wewers MW. Taxol enhances but does not induce interleukin-1 beta and tumor necrosis factor-alpha production. *Journal of Laboratory and Clinical Medicine*. 1993; 122:374-381.

19. Allen JN, Davis WB. State of the Art: The Eosinophilic Lung Diseases. *American Journal of Respiratory and Critical Care Medicine*. 1994; 150:1423-1438.

20. Allen JN, Moore SA, Pope-Harman AL, Marsh CB, Wewers MD. Immunosuppressive properties of surfactant an plasma on alveolar macrophages. *Journal of Laboratory and Clinical Medicine*. 1995; 125:356-69.

21. Smith RE, Thornton DE, Allen, JN. A Phase II Trial Of Taxol In Squamous Cell Carcinoma Of The Head And Neck With Correlative Laboratory Studies. *Seminars in Oncology*. 1995; 22S:41-46.

22. O'Brien JM, Moore SA, Wewers MD, Allen JN. Taxol and colchicine increase proIL-1 beta production without affecting processing and release of mature IL-1 beta. *Journal of Immunology*. 1995; 154:4113-4122.

23. Allen JN, Liao Z, Wewers MD, Altenberger EA, Moore SA, Allen ED. Detection of interleukin-5 and interleukin-1 receptor antagonist in bronchoalveolar lavage in acute eosinophilic pneumonia. *Journal of Allergy and Clinical Immunology*. 1996, 97:1366-1374.

24. Allen JN, Moore SA, Liao Z, Wewers MD. Changes in mononuclear phagocyte microtubules after endotoxin stimulation: I. Changes in microtubule stability. *American Journal of Respiratory Cell and Molecular Biology*. 1997, 16:119-26.

25. Allen JN, Liao Z, Moore SA, Wewers MD. Changes in mononuclear phagocyte microtubules after endotoxin stimulation: II. Changes in microtubule composition. *American Journal of Respiratory Cell and Molecular Biology*. 1997, 16:127-32.

26. Pope-Harman AL, Davis WB, Christoforidis AJ, Allen ED, Allen JN. Acute

eosinophilic pneumonia: A summary of fifteen cases and review of the literature. *Medicine* 1996; 75:334-332.

27. King MA, Pope-Harman AL, Allen JN, Christoforidis GA, Christoforidis AJ. Acute eosinophilic pneumonia: Radiologic and clinical features. *Radiology*. 1997; 203:715-9.

28. Knoell DL, Pierson JF, Marsh CB, Allen JN, Pathak DS. Measurement of outcomes in adult patients receiving pharmaceutical care in a comprehensive asthma clinic. *Pharmacotherapy*. 1998; 18:1365-74.

29. Shaffer JP, Allen JN. The use of expandable metal stents to facilitate extubation in patients with large airway obstruction. *Chest*. 1998; 114:1378-82.

30. Knoell DL, Allen JN. Churg-Strauss syndrome associated with zafirlukast. *Chest*. 1998; 114:332-3.

31. Gorman TE, Julius CJ, Barth R, Ng A, Kennedy MS, Prior TW, Allen J, Lasky L. Transfusion-associated graft-versus host disease: A fatal case caused by blood from an unrelated HLA homozygous donor. *American Journal of Clinical Pathology*. 2000; 113:732-7.

32. Grecula JC, Smith RE, Rhoades CA, Sharma P, Agrawal A, Zhang H, Allen J, Goldman FP, Young D, Schuller D. Phase II Trial: Induction paclitaxel in previously untreated, resectable, advanced squamous cell carcinoma of head and neck. *Cancer*. 2000;89:2587-96.

33. Massick DD, Yao S, Powell DM, Griesen D, Hobgood T, Allen JN, Schuller DE. Bedside tracheostomy in the intensive care unit: a prospective randomized trial comparing open surgical tracheostomy with endoscopically guided percutaneous dilational tracheotomy. *Laryngoscope*. 2001; 111:494-500.

34. Allen JN, Magro CM, King MA. The Eosinophilic Pneumonias. *Seminars in Respiratory and Critical Care Medicine*. 2002; 2:127-134.

35. Magro CM, Allen J, Pope-Harman A, Waldman WJ, Moh P, Rothrauff S, Ross P. The role of microvascular injury in the evolution of idiopathic pulmonary fibrosis. *Am J Clin Pathol* 2003; 119: 556-67.

36. Allen JN. Drug induced eosinophilic lung disease. *Clinics In Chest Medicine*. 2004; 25:77-88.

BOOK CHAPTERS:

1. Allen JN, Davis WB. Eosinophils and the lung. In: *The Lung: Scientific Foundations*, edited by Crystal RG, West J, Weibel E, and Barnes PL. New York: Raven Press, Ltd., 1996.

2. Allen JN. Airway Stents; Self-expandable Metallic. In: *Interventional Bronchoscopy* (editors: John F. Beamis, M.D., Praveen Mathur, M.B.B.S., and Athul

Mehta, M.D.), 2004.

3. Allen JN. Eosinophilic Pulmonary Syndromes. In: Textbook of Pulmonary Diseases, Seventh Edition. (editors: Crapo JD, Glassroth J, Karlinsky J, and King TE. 2003. 521-38.

ABSTRACTS:

1. Clendenon NR, Gordon WA, Allen JN. Early alteration in fluid and electrolyte levels following experimental spinal cord injury. Society for Neuroscience Abstracts. 1981; 7.

2. Clendenon NR, Gordon WA, Nesham ME, Allen JN. Traumatically induced changes in extracellular space in the rat spinal cord. Society for Neuroscience Abstracts. 1983; 9:164.

3. Allen JN, Pacht ER, Davis WB. Respiratory failure with increased bronchoalveolar lavage eosinophils. Clinical Research. 36: 854A, 1988.

4. Allen JN, Pacht ER, Davis WB. Idiopathic eosinophilic pneumonia: a reversible form of acute respiratory failure. American Review of Respiratory Disease. 139: A274, 1989.

5. Allen JN, Davis WB, Pacht ER. The significance of bronchoalveolar lavage (BAL) eosinophilia. American Review of Respiratory Disease. 141: A890, 1990.

6. Allen JN, Herzyk DJ, Wewers MD. Colchicine has dyscoordinate effects on interleukin-1 (IL-1) and tumor necrosis factor (TNF) release by human mononuclear phagocytes. FASEB Journal. 4: A1751, 1990.

7. Allen JN, Herzyk DJ, Wewers MD. The effect of colchicine on interleukin-1 (IL-1) and tumor necrosis factor (TNF) release by human mononuclear phagocytes in vitro. American Review of Respiratory Disease. 141: A677, 1990.

8. Allen JN, Herzyk DJ, Wewers MD. Interleukin-1b production by human whole blood. Clinical Research. 38: 872A, 1990.

9. Allen JN, Herzyk DJ, Wewers MD. Plasma increases interleukin-1b (IL-1b) release by monocytes but not alveolar macrophages in vitro. American Review of Respiratory Disease. 143:234A, 1991.

10. Allen ED, Allen JN, McCoy KS, Wewers MD. Comparison of interleukin-1b production: normals vs. cystic fibrosis patients. Pediatric Pulmonology. 1991; 6:305.

11. Allen JN, Murray K, Weiland JW, Herzyk DJ, Wewers MD. Cytokine production during cardiopulmonary bypass. Clinical Research. 1991; 39:753A.

12. Herzyk DH, Allen JN, Wewers MD. Detectability of natural interleukin 1b precursor. European Congress of Clinical Chemistry. 1991.

13. Allen JN, Herzyk DJ, Wewers MD. Surfactant suppresses interleukin-1b and

tumor necrosis factor- α release by human alveolar macrophages. *American Review of Respiratory Diseases*. 1992; 145: A875.

14. Allen JN, Moore SA, Wewers MD. Taxol enhances but does not stimulate interleukin-1 β and tumor necrosis factor- α production. *Clinical Research*. 1992; 40:744A.

15. Allen JN, Marsh CB, Moore SA, Wewers MD. Surfactant and plasma exert immunosuppressive effects on alveolar macrophage cytokine production. *Clinical Research*. 1993; 41:689A.

16. Pope-Harman AL, Davis WB, Allen ED, Christoforidis AJ, Allen JN. Radiographic manifestations of acute eosinophilic pneumonia. *American Journal of Respiratory and Critical Care Medicine*. 1994; A431.

17. Pope-Harman AL, Moore SA, Wewers MD, Allen JN. Inhibition of cytokine release and CD14 expression by surfactant component phospholipids. *American Journal of Respiratory and Critical Care Medicine*. 1994; A94.

18. Allen JN, Moore SA, Jurist U, Wewers MD. Alveolar macrophage and blood monocyte microtubules undergo functional and structural changes after endotoxin stimulation. *American Journal of Respiratory and Critical Care Medicine*. 1994; 149:A239.

19. Allen JN, Liao Z, Moore SA, Allen ED, Wewers MD. Local production of interleukin-5 and interleukin-1 receptor antagonist in acute eosinophilic pneumonia. *Clinical Research*. 1994; 42:382A.

20. Pope-Harman AL, Davis WB, Allen ED, Allen JN. A summary of twelve cases of acute eosinophilic pneumonia. *Clinical Research*. 1994; 42:372A.

21. O'Brien JA, Moore SA, Wewers MD, Allen JN. Taxol and colchicine increase proIL-1 β without affecting processing and release of mature IL-1 β . *Clinical Research*. 1994; 42:397A.

22. Pope-Harman AL, Davis WB, Allen ED, Allen JN. Acute eosinophilic pneumonia: a review of twelve cases. *Chest*. 1994; 106:156S.

23. Allen JN, Liao Z, Wewers MD. Alveolar macrophage CD43: Functional qualities, size, and effects on cytokine production. *American Journal of Respiratory and Critical Care Medicine*. 1995; 151:A339.

24. Pope-Harman AL, Wewers MD, Allen JN. Surfactant phospholipid effects on receptors for endotoxin in alveolar macrophages and blood monocytes. *American Journal of Respiratory and Critical Care Medicine*. 1995; 151:A309.

25. Allen JN, Wewers MD, Liao Z. The role of microtubules in neutrophil chemotaxis to interleukin-8. *Journal of Investigative Medicine*. 1995; 43:442.

26. Allen JN, Wewers ME, Liao Z. Microtubule disruption inhibits alveolar macrophage production of IL-8 and inhibits neutrophil chemotaxis to IL-8.

American Journal of Respiratory and Critical Care Medicine. 1996; 153:A247.

27. Knoell DL, Pierson JF, Pathak DS, Marsh CB, Allen JN. Pharmacist interventions in a comprehensive asthma clinic. International Pharmaceutical Abstracts. 1996: 2256.

28. Allen JN, Greenspan PE, Wewers MD, Drake JE, Clanton TL. Positional changes in total lung capacity and diffusing capacity in alpha-1 antitrypsin deficiency. American Journal of Respiratory and Critical Care Medicine. 1996, 153:A751.

29. Pendarvis RW, Irsik RD, Allen JN, King MA, Spigos DG. Endobronchial stents: Pictorial of radiographic changes. Radiology. 1996, 201s:470.

30. Allen JN, Liao Z. Pharmacologic inhibition of human mononuclear cell interleukin-5 production. American Journal of Respiratory and Critical Care Medicine. 1997, 155:A750.

31. Shaffer JP, Allen JN. The use of expandable metal stents to facilitate extubation in patients with large airway obstruction. Chest. 1997, 112:25S.

32. Gorman T, Julius C, Ng A, Barth R, Becker G, Allen J, Pidwell D, Lasky L. Transfusion-associated graft-vs-host disease: A fatal case caused by blood from an unrelated HLA homozygous donor. Transfusion. 1997.

33. Allen JN, Shaffer JP. Complications and success rates of 3 airway stents. American Journal of Respiratory and Critical Care Medicine. 1998, 157:A705.

34. Shaffer JP, Allen JN. Complications and success rates of three flexible metal airway stents. Am J Resp Crit Care Med 2000; 161:A234

35. Hollenbeck S, Allen JN. The use of the Rusch-Y tracheobronchial stent in patients requiring mechanical ventilation. Chest 2000.

36. Shaffer JP, Allen JN, Prior RB. Detection of endotoxin in talc preparations used for pleurodesis. Chest 2000.

37. White D, Kris M, Otterson GA, Imondi A, Allen JN, Sharma S. Phase I clinical and pharmacologic study of inhaled doxorubicin in adults with advanced solid tumors affecting the lungs. Journal of Clinical Oncology 2001.

38. Ali N, Allen J, Pope-Harman A, Ross P, Magro C. Cytomegalovirus (CMV) infection as a cause of alveolar hemorrhage in the immunocompetent patient. American Journal of Respiratory and Critical Care Medicine 2002: A49.

39. Magro C, Pope-Harman A, Allen J, Ross P, Morrison C, Ferri C, Crowson AN. Immuofluorescence testing as an adjunct in the diagnosis of interstitial lung disease (ILD). American Journal of Respiratory and Critical Care Medicine 2002: C44.

40. Magro C, Pope-Harman A, Allen J, Waldman J, Ross P. Microangiopathic fibrosing pneumonitis. American Journal of Respiratory and Critical Care

Medicine 2002: A49.

41. Morales JE, Iltchev D, Allen JN, Sood N. Isolated Takayasu disease of the pulmonary artery mimicking recurrent pulmonary embolism. Chest 2003; 124:298S.

42. Morales JE, Iltchev D, Allen JN. Life-threatening diffuse alveolar hemorrhage related to crack cocaine use: spontaneous resolution without steroids. Chest 2003; 124:243S.

PRESENTATIONS:

National Meetings:

1. Spoleto Pulmonary Symposium; Charleston, South Carolina 1991: "Pulmonary Complications of Systemic Disease".
2. Charleston Pulmonary Symposium; Charleston, South Carolina 1992: "Pulmonary Complications of AIDS".
3. American Thoracic Society; Boston, Massachusetts 1992: "The Eosinophilic Pneumonias".
4. Charleston Pulmonary Symposium; Charleston, South Carolina 1993: "Pulmonary Embolic Syndromes".
5. Fox Chase Cancer Symposium; Boca Raton, Florida 1994: "Paclitaxel with Correlated Science".
6. Charleston Pulmonary Symposium; Charleston, South Carolina 1994: "Pulmonary Complications of AIDS".
7. Charleston Pulmonary Symposium; Charleston, South Carolina 1995: "The Eosinophilic Lung Diseases".
8. American Thoracic Society; New Orleans, Louisiana 1996: "Acute Eosinophilic Pneumonia".
9. Charleston Pulmonary Symposium; Charleston, South Carolina 1997: "Interventional Bronchoscopy".
10. American College of Chest Physicians New Orleans, Louisiana 1997 "Eosinophilic Lung Disease"
11. American Thoracic Society; Chicago, Illinois 1998: "Eosinophilic Lung Disease"
12. 23rd Annual Critical Care Course Medical College of Georgia; Sea Island, Georgia 2001: "Breathing New Life Into Old Diseases - Update On Mechanical Ventilation"
13. 23rd Annual Critical Care Course Medical College of Georgia; Sea Island, Georgia 2001: "Plumbing Repair In The ICU - Approach To Large Airway Obstruction"
14. Medical University of South Carolina Department of Internal Medicine Grand Rounds 2002: "The Eosinophilic Lung Diseases"
15. Ohio Thoracic Society Annual Meeting 2003: "Idiopathic Pulmonary Fibrosis"
16. American College of Chest Physicians, Orlando, Florida, 2003. "Pro-Con: Early Idiopathic Pulmonary Fibrosis Should Be Treated"
17. University Hospitals Consortium webcast 2004: "Moderate and Deep Sedation"
18. American Academy of Allergy, Asthma, and Immunology Annual Meeting 2005: "The Eosinophilic Lung Diseases"

Ohio State University:

1. OSU Department of Internal Medicine Grand Rounds 1990: "Pulmonary Complications of AIDS".
2. OSU Department of Internal Medicine Grand Rounds 1991: "Acute Eosinophilic Pneumonia".
3. OSU Department of Internal Medicine Grand Rounds 1992: "Asthma Update: Common Myths and Current Controversies".
4. Physical Medicine Grand Rounds 1992: "Non-Invasive Ventilatory Aides".
5. Emergency Medicine Grand Rounds 1992: "Pulmonary Embolism".
6. OSU Department of Internal Medicine Review Course 1992: "Interstitial Lung Diseases".
7. Symposium on Pulmonary Infections 1993: "Pulmonary Complications of AIDS".
8. OSU Department of Internal Medicine Grand Rounds 1993: "Easily Mis-Diagnosed Pulmonary Infections".
9. OSU Department of Internal Medicine Grand Rounds 1994: "Lung Cancer: Update in Diagnosis, Staging, and Treatment".
10. Ohio Medical Education Network (OMEN) 1994: "Diagnosis and Treatment of Lung Cancer".
11. 3rd Annual Pulmonary Symposium 1995: "When The Cause Of Respiratory Failure Is Non-Infectious".
12. Ohio Medical Education Network (OMEN) 1995: "Tuberculosis Update".
13. 8th Annual Cardiology Symposium 1995: "Acute Ventilator Therapy".
14. OSU Department of Internal Medicine Grand Rounds 1995: "Update on the Treatment of COPD".
15. OSU Department of Internal Medicine Grand Rounds 1996: "The Eosinophilic Lung Diseases".
16. 4th Annual Pulmonary Symposium 1996: "Non-Invasive Ventilation in COPD".
17. Ohio Medical Education Network (OMEN) 1996: "Update on COPD".
18. OSU Department of Internal Medicine Grand Rounds 1996: "Asthma Update".
19. Ohio Medical Education Network (OMEN) 1997: "Update in Mechanical Ventilation".
20. OSU Department of Internal Medicine Grand Rounds 1997: "Approach To Large Airway Obstruction".
21. OSU Department of Obstetrics and Gynecology Grand Rounds 1997: "Pulmonary Thromboembolism".
22. Ohio Medical Education Network (OMEN) 1998: "Pulmonary Quiz".
23. 5th Annual Pulmonary Symposium 1998: "Tracheobronchial Stents".
24. OSU Respiratory Therapy Update Symposium 1998: "Tracheobronchial Stents".
25. OSU Respiratory Therapy Update Symposium 1998: "Is There A Best Way To Wean?".
26. OSU Case Managers Symposium 1998 "The Pulmonary Patient In Long Term Acute Care Hospitals".
27. 6th Annual Pulmonary Symposium 1999: "Pulmonary Thromboembolism".
28. 6th Annual Pulmonary Symposium 1999: "Lung Cancer".
29. OSU Department of Internal Medicine Grand Rounds 1999: "Pulmonary Embolism".
30. OSU Department of Physical Medicine Grand Rounds 1999: "Pulmonary Embolism".
31. Columbus Children's Hospital Department of Pediatrics Grand Rounds 1999: "Pulmonary Embolism".
32. OSU Department of Internal Medicine Grand Rounds 1999: "Lung Cancer Update".
33. 7th Annual Pulmonary Update 2000: "Lung Cancer treatment".
34. OSU Department of Internal Medicine Grand Rounds 2000: "Pulmonary Fibrosis".

35. OSU Department of Internal Medicine Grand Rounds 2000: "Hypercoaguable States".
36. 8th Annual Pulmonary Update 2001: "Pulmonary Embolus"
37. 8th Annual Pulmonary Update 2001: "Idiopathic Pulmonary Fibrosis"
38. OSU Department of Internal Medicine Grand Rounds 2001: "CPC: Scleroderma Lung Disease"
39. OSU Department of Internal Medicine Grand Rounds 2001: "ARDS: Improved Mortality For The Wrong Reasons"
40. 9th Annual Pulmonary Update 2002: "Mechanical Ventilation"
41. OSU Department of Internal Medicine Grand Rounds 2003: "Pro-Con: Controversies in Pulmonary Embolism"
42. 10th Annual Pulmonary Update 2003: "Interstitial Lung Disease"
43. OSU East Hospital Grand Rounds 2003: "Pulmonary Embolism"
44. OSU Department of Anesthesiology Grand Rounds 2004: "Pulmonary Function Testing"
45. 11th Annual Pulmonary Update 2004: "Interventional Bronchoscopy"
46. OSU Department of Internal Medicine Grand Rounds 2004: "Interventional Bronchoscopy"
47. OSU Department of Surgery Grand Rounds 2005: "Pre-operative Pulmonary Evaluation"

Non-Academic Institutions:

1. Lancaster-Fairfield Community Hospital; Lancaster, Ohio 1991: "Pulmonary Complications of AIDS".
2. Columbus VA Clinic; Columbus, Ohio 1991: "Pulmonary Complications of AIDS".
3. Chillicothe VA Hospital; Chillicothe, Ohio 1992: "Pulmonary Complications of AIDS".
4. Chillicothe VA Hospital; Chillicothe, Ohio 1992: "Tuberculosis Update".
5. Chillicothe VA Hospital; Chillicothe, Ohio 1992: "Pulmonary Complications of Systemic Disease".
6. Chillicothe VA Hospital; Chillicothe, Ohio 1992: "Asthma Update: Common Myths and Current Controversies".
7. Chillicothe VA Hospital; Chillicothe, Ohio 1993: "Pulmonary Embolism".
8. Columbus VA Clinic; Columbus, Ohio 1993: "Asthma Update: Common Myths and Current Controversies".
9. Hickam Air Force Base Medical Clinic; Honolulu, Hawaii 1993: "Pulmonary Complications of AIDS".
10. Chillicothe VA Hospital; Chillicothe, Ohio 1993: "Unusual Pulmonary Infections".
11. Columbus VA Clinic; Columbus, Ohio 1994: "Lung Cancer: Update in Diagnosis, Staging, and Treatment".
12. Chillicothe VA Hospital; Chillicothe, Ohio 1994: "Lung Cancer: Update in Diagnosis, Staging, and Treatment".
13. Chillicothe VA Hospital; Chillicothe, Ohio 1994: "Evaluation and Management of Shock".
14. Chillicothe VA Hospital; Chillicothe, Ohio 1995: "Tuberculosis Update".
15. Columbus VA Clinic; Columbus, Ohio 1995: "Tuberculosis Update".
16. Bethesda Hospital; Zansville, Ohio 1995: "Update on the Treatment of COPD".
17. Doctors's Hospital; Columbus, Ohio 1995: "Mechanical Ventilation".
18. Chillicothe VA Hospital; Chillicothe, Ohio 1995: "Update on COPD".

19. Columbus VA Clinic; Columbus, Ohio 1995: "Update on COPD".
20. Ohio Thoracic Society Spring Meeting; Columbus, Ohio 1996: "Ventilator Weaning".
21. Mount Carmel Medical Center Grand Rounds 1996: "Non-Invasive Ventilation".
22. Columbus VA Clinic; Columbus, Ohio 1997: "Update on Asthma".
22. Chillicothe VA Hospital; Chillicothe, Ohio 1997: "Update on Asthma".
23. Northside Hospital; Youngstown, Ohio 1997: "Mechanical Ventilation 1997".
24. Doctor's Hospital Department of Emergency Medicine 1997: "Community-Acquired Pneumonia"
25. Cox Medical Center, Springfield, MO, 1998: "Tracheobronchial Stents".
26. Grady Hospital, Delaware, OH, 1998: "Asthma Update"
27. Mt. Carmel Hospital, Columbus, OH, 1998: "Tuberculosis Update 1998"
28. Chillicothe VA Hospital; Chillicothe, Ohio 1999: "Pulmonary Embolism"
29. Grady Hospital, Delaware, OH, 1999: "Tuberculosis Update 1999"
30. Camden Clark Hospital, Parkersburg, WV, 1999: "Pulmonary Embolism"
31. Clark County Medical Association, Springfield, OH, 1999: "Pulmonary Embolism"
32. Chillicothe VA Hospital; Chillicothe, Ohio, 2000: "Pulmonary Fibrosis"
33. Springfield Mercy Medical Center, Springfield, OH, 2000: "Pulmonary Embolism"
34. Chillicothe VA Hospital; Chillicothe, Ohio, 2001: "Pulmonary Embolism"
35. Camden Clark Hospital, Parkersburg, WV 2001: "ARDS Update"
36. Chillicothe VA Hospital; Chillicothe, Ohio, 2001: "ARDS Update"
37. Ohio University; Columbus, Ohio, 2003: "Pulmonary Embolism"
37. Columbus Children's Hospital, 2005: "Pulmonary Embolism"
38. Lakewood Hospital, Cleveland, Ohio, 2005: "Eosinophilic Lung diseases"

The Ohio Medical Education Network: Editor and moderator for a weekly nationally televised continuing medical education television program

1998 - 1999: 26 programs

1999 - 2000: 28 programs

2000 - 2001: 27 programs

2001 - 2002: 28 programs

OSU MedNet 21: Editor and moderator for a weekly webcast continuing medical education program

2002 - 2003: 20 programs

2003 - 2004: 30 programs

2004-2005: 30 programs

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